

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 13-569V

April 25, 2014

Not to be Published

BRITTENY DEWS, by her Mother and Next
Friend, DAWN BROWN,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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HPV vaccine; desmoplastic
small round cell cancer; petitioner
moves for judgment on the record;
no medical expert support

Elaine W. Sharp, Marblehead, MA, for petitioner.

Deborah A. Filteau Begley, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION¹

Petitioner filed a petition on August 12, 2013, under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10–34 (2006). Petitioner alleges that human papillomavirus vaccine (“HPV” or “Gardasil”) administered to her daughter Britteny Dews (“Britteny”) in

¹ Because this decision contains a reasoned explanation for the special master’s action in this case, the special master intends to post this decision on the United States Court of Federal Claims’s website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to redact such information prior to the document’s disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access.

August and October 2009 caused her desmoplastic small cell cancer from which she died on August 12, 2011. Pet. ¶¶ 2–5.

On March 14, 2014, petitioner filed a vaccination record showing Britteny received HPV vaccine on January 8, 2008. Med. recs. Ex. 9, at 1. She did not file proof of HPV vaccination for any other date.

On April 25, 2014, respondent filed her Rule 4(c) Report, stating that petitioner did not offer any proof from either Britteny’s treating physicians or an expert medical doctor that HPV vaccine caused Britteny’s cancer, thus failing to make a prima facie case.

On April 25, 2014, the undersigned held a telephonic status conference with counsel, during which petitioner’s counsel stated petitioner consented to dismissal of the case.

On April 25, 2014, petitioner filed a Motion for Judgment on the Record, stating that her counsel had diligently pursued “all avenues of causation” and consulted with a reviewing physician on the case and that petitioner “understands the difficulties in pursuing this case further and assents to the relief sought in this motion” Pet’r’s Mot. at 1.

On April 25, 2014, after petitioner filed her Motion for Judgment on the Record, she filed Opinion and Course of Action Recommendation of Leonard R. Worden, Ph. D., M.D. Pet’r’s Ex. 10. In his opinion, Dr. Worden states he cannot determine whether HPV retains any residual viral DNA. Id. at 2. He states he is unaware of any specific cases of cancer related to HPV. Id. He writes, “It is my opinion that – without further investigation through the discovery process in a court of law – we have no way to establish that Brittany’s [sic] cancer was caused by Gardasil.” Id. He recommends obtaining an aliquot of the vial of the specific Gardasil vaccine Britteny received in order to rule out whether or not any live virus or viral DNA existed in that specific batch. Id. Then, Dr. Worden recommends obtaining tissue from Britteny’s tumors in order to rule out the presence of HPV or viral DNA in the tumor samples. Id. If live virus or viral DNA were found in either HPV vaccine or in Britteny’s tumor sample, Dr. Worden thinks there would be a good faith basis to proceed with the case. Id.

The undersigned rules that petitioner has failed to make a prima facie case that HPV vaccine caused Britteny’s unfortunate cancer and regrettable death, and dismisses this case.

FACTS

Britteny was born on February 1, 1989.

On January 8, 2008, she received HPV vaccine. Med. recs. Ex. 9, at 1.

On June 15, 2009, she had an abdominal CT after complaining of abdominal pain, diarrhea, and constipation. Med. recs. Ex. 4, at 12. The result was normal except for a follicular left ovarian cyst. Id.

On March 31, 2010, Britteny had a CT scan that revealed a large mass in her abdomen. Id. at 10–11.

On May 19, 2010, she had a CT-guided biopsy which revealed that the mass in her abdomen was an invasive, malignant tumor with features of a desmoplastic small round cell tumor. Med. recs. Ex. 2, at 97. The tumor rapidly increased in mass and size. Id. at 43, 47.

On December 2, 2010, a CT scan showed marked progression of Britteny's cancer. Med. recs. Ex. 1, at 24.

On August 12, 2011, Britteny died from metastatic desmoplastic small round cell abdominal cancer from which, according to the death certificate, she had suffered for 15 months. Med. recs. Ex. 8, at 1.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen v. Sec’y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[.]” the logical sequence being supported by “reputable medical or scientific explanation[.]” i.e., “evidence in the form of scientific studies or expert medical testimony[.]”

Althen, 418 F.3d at 1278.

Without more, “evidence showing an absence of other causes does not meet petitioner’s affirmative duty to show actual or legal causation.” Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

The Vaccine Act does not permit the undersigned to rule for petitioner based on her claims alone, “unsubstantiated by medical records or by medical opinion.” 42 U.S.C. § 300aa-13(a)(1) (2006).

The medical records do not support petitioner’s allegation that HPV vaccine caused Britteny’s desmoplastic small round cell cancer. Petitioner has not filed an expert report from a medical doctor in support of her allegation. The only medical expert report she filed was from Dr. Worden, who states he is unaware of HPV vaccine causing any specific cancer cases and also

states that without analyzing the specific vial of HPV vaccine Britteny received in 2008 and testing tissue samples from her tumors to look for live virus or viral DNA in either the vaccine vial or tumors, there would not be a good faith basis to proceed.

Without either medical record or expert medical support that HPV vaccine can cause desmoplastic small round cell cancer, petitioner has failed to satisfy prong one of Althen. Because petitioner has failed to prove that HPV vaccine can cause desmoplastic small round cell cancer, she has also failed to prove that HPV vaccine did cause Britteny's desmoplastic small round cell cancer. Petitioner has failed to satisfy prong two of Althen. In addition, petitioner has failed to prove that an interval between January 8, 2008 (the date of Britteny's HPV vaccination) and early 2010 (Britteny's cancer diagnosis), which is an interval of over two years, is appropriate to support causation of desmoplastic small round cell cancer from HPV vaccine. Thus, petitioner has failed to satisfy prong three of Althen.

Petitioner has failed to make a prima facie case. This petition is hereby **DISMISSED**.

CONCLUSION

This petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment herewith.²

IT IS SO ORDERED.

Dated: April 25, 2014

s/Laura D. Millman

Laura D. Millman
Special Master

² Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.